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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,752	03/26/2001	Olga Bandman	PF-0559 USN	7326

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Incyte Genomics Inc
Legal Department
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Palo Alto, CA 94304

EXAMINER

PAK, YONG D

ART UNIT PAPER NUMBER

1652

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/743,752	BANDMAN ET AL.	
	Examiner	Art Unit	
	Yong D Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-45 is/are pending in the application.
- 4a) Of the above claim(s) 21,22,35-39 and 41-45 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30 is/are allowed.
- 6) ☒ Claim(s) 23,26-28,31-34 and 40 is/are rejected.
- 7) ☒ Claim(s) 24,25 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on March 22, 2004, amending claims 21, 30 and 31, has been entered. This application is a 371 of PCT/US99/16164.

Claims 21-45 are pending.

Election/Restrictions

Applicant's argue that Group I and Group III share a special technical feature. This is not found persuasive. Group I and Group III lacks a special technical feature because for a DNA and protein group to share a special technical feature, claims drawn to the DNA must be DNA sequences that encode the structure of the protein in the claims drawn to the protein (see PCT administrative instructions Example 17). In the instant invention, the DNA and proteins claims to not correspond to each other in that claims are drawn to DNA encoding SEQ ID NO:1 and other unrelated polypeptides. For example, the polynucleotides of claim 31 do not correspond to claim 21. Therefore, the technical feature linking Groups I and III is lacking.

The requirement is still deemed proper and is therefore made FINAL.

Notice of Possible Rejoinder: The Examiner notes that if claims 23 and 25 are found directed to an allowable product, then claims 39 and 41-42, which are directed to the process of making or using the patentable product, respectively, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March

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26, 1996 (1184 O.G. 86; see also MPEP 821.04, *In re Ochiai*, and *In re Brouwer*).

Since process claims 39 and 41-42 would be rejoined and fully examined for patentability under 37 CFR 1.104, applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Claim 30 is directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 32-34 and 40, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Process claims 32-34 and 40 are hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 21-22, 35-39 and 41-45, not directed to the process of making or using the patentable product, will not be rejoined.

Claims 21-22, 35-39 and 41-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

Claim Objections

Claims 23-30 are objected to as being dependent upon a non-elected base claim, and should be rewritten in independent form including all of the limitations of the base claim and any intervening claims. The claims have been interpreted to include all the limitations of its base claim and any intervening claims.

Response to Arguments

Claim Rejections - 35 USC § 112

Applicant's arguments, filed on March 22, 2004, with respect to the rejection claims 29 and 30 under 35 USC 112, 1st paragraph have been fully considered and are persuasive.

Applicant's arguments, filed on March 22, 2004, with respect to the rejection claims 23, 26-28 and 31 under 35 USC 112, 1st paragraph have been fully considered and are not persuasive.

Claims 23, 26-28, 31-34 and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that the present claims are specifically defined through the recitation of chemical structure. The examiner disagrees. A description of only 20-60 nucleic acids, which represent less than 5% of the whole structure of the DNA molecule, amount to insufficient description of the structure of the DNA molecules in these claims. The specification does not contain any disclosure of the structure and function of all DNA fragments or portions of SEQ ID NO:3. The genus of DNA that comprise these above fragments and portions of SEQ ID NO:3 is a large variable genus with the potentiality of encoding many different proteins. Therefore, many structurally and

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functionally unrelated DNA are encompassed within the scope of these claims, including partial DNA sequences. The specification fails to describe any other representative species by any identifying characteristics or properties other than the "functionality" of encoding an immunogenic fragment of SEQ ID NO:1 (claims 23 and 26-28) or consisting of any 60 nucleotides of SEQ ID NO:3 without a defined function (claim 31) or the functionality of being a probe comprising an undefined structure (claims 32-34 and 40) and fails to provide any structure: function correlation present in all members of the claimed genus.

Applicants also argue that the present claims do not define a genus which is highly variant. The examiner disagrees. Structurally, the claims are drawn to only 20-60 nucleic acids, which represent less than 5% of the whole structure of SEQ ID NO:3. Functionally, claim 31 is drawn to 60 oligomer of SEQ ID NO:3 having undefined function.

Applicants also argue that the state of the art at the time the present invention was further advanced. While it is true that the state of the art regarding isolation/cloning of polynucleotides has been improving, one skilled in the art would not recognize that the present inventions were in possession of such a diverse, highly variant genus of polynucleotides, for reasons stated above.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 23, 26-28, 31-34 and 40.

Claims 23, 26-28, 31-34 and 40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA encoding the polypeptide of SEQ ID NO:1 and variants thereof having alcohol dehydrogenase activity, does not reasonably provide enablement for DNA molecules of unknown structure. The specification also does not reasonably provide enablement for polynucleotides encoding polynucleotide having unknown function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments are directed mainly towards polynucleotide having 90% homology to SEQ ID NO:3. Arguments are not directed towards fragments/portions of SEQ ID NO:3.

The claims are drawn to DNA fragments of SEQ ID NO:3 or portions of SEQ ID NO:3 having unlimited structure and/or encoding a polypeptide with SPHK activity or unknown activity. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of constructs broadly encompassed by the claims. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

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Applicant's arguments, filed on March 22, 2004, with respect to the rejection claims 23 and 26-31 under 35 USC 112, 2nd paragraph have been fully considered and are persuasive. The rejection of claims 23 and 26-31 has been withdrawn.

Claim Rejections - 35 USC § 102

Applicant's arguments, filed on March 22, 2004, with respect to the rejection claims 23 and 31 under 35 USC 102(b) as being anticipated by Bonaldo et al. have been fully considered and are persuasive. The rejection of claims 23 and 31 has been withdrawn.

Applicant's arguments, filed on March 22, 2004, with respect to the rejection claims 23 and 26-28 under 35 USC 102(b) as being anticipated by Gabrielli et al. have been fully considered and are persuasive. The rejection of claims 23 and 26-28 has been withdrawn.

Allowable Subject Matter

Claim 30 is allowed.

Conclusion

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner


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